
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K
CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): November 4, 2013

TherapeuticsMD, Inc.

(Exact Name of Registrant as Specified in its Charter)

Nevada

(State or Other
Jurisdiction of Incorporation)

000-16731

(Commission File Number)

87-0233535

(IRS Employer
Identification No.)

6800 Broken Sound Parkway NW,
Third Floor
Boca Raton, FL 33487

(Address of Principal Executive Office) (Zip Code)

Registrant's telephone number, including area code: (561) 961-1900

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2 below):

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act
(17 CFR 240.13e-4(c))

Item 2.02. Results of Operations and Financial Condition.

As described in Item 7.01, we are furnishing this Current Report on Form 8-K in connection with the disclosure of information during a conference call and webcast on November 4, 2013 discussing our third quarter fiscal 2013 financial results. The disclosure provided in Item 7.01 of this Current Report on Form 8-K is hereby incorporated by reference into this Item 2.02.

The information in this Current Report on Form 8-K (including the exhibit) is furnished pursuant to Item 2.02 and shall not be deemed to be “filed” for the purpose of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section.

Item 7.01. Regulation FD Disclosure.

We are furnishing this Current Report on Form 8-K in connection with the disclosure of information during a conference call and webcast on November 4, 2013 discussing our third quarter fiscal 2013 financial results. The transcript of the conference call and webcast is included as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K (including the exhibit) is furnished pursuant to Item 7.01 and shall not be deemed to be “filed” for the purpose of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. This Current Report on Form 8-K will not be deemed an admission as to the materiality of any information in the Current Report on Form 8-K that is required to be disclosed solely by Regulation FD.

The text included with this Current Report on Form 8-K and the replay of the conference call and webcast on November 4, 2013 is available on our website located at www.therapeuticsmd.com, although we reserve the right to discontinue that availability at any time.

Certain statements contained in this Current Report on Form 8-K may be deemed to be forward-looking statements under federal securities laws, and we intend that such forward-looking statements be subject to the safe harbor created thereby. Such forward-looking statements include, but are not limited to, statements regarding the impact of the increases in the number of physicians writing prescriptions for our product, the productivity of our sales force, the average net sales price of our product, and the new products introduced in 2012; the impact of development of our new hormone replacement therapy product candidates and the initiation of two clinical trials; the impact of the prenatal business on our revenue, our ability to develop infrastructure that will be crucial to launching our hormone therapy products going forward, our brand recognition, and on our ability to build trust with women; our belief that our representatives are building strong relationships with the OB/GYN community, and that the OB/GYN community will be our key call point for our hormone therapy products; our belief in the merits of our sales and distribution network; the focus of our business; our belief that the hormone therapy is an area that has largely been overlooked for close to a decade; our expectation that the first NDA we file will be for our low-dose oral progesterone candidate; our belief in the benefits and attributes of our proposed hormone therapy products; our goals regarding the clinical development of our proposed hormone therapy products; the designs of clinical trials for our proposed hormone therapy products; our expectation regarding when we will announce data from a phase 3 clinical trial and when we will file an NDA for our low-dose oral progesterone candidate; enrollment in a phase 3 clinical trial for our combination drug product and our goals for enrollment in such trial; our expectation regarding when we will announce data from a phase 3 clinical trial and when we will file an NDA for our combination drug candidate; the size of the vulvar and vaginal atrophy market; our belief that our estradiol VagiCap™ product will give us a competitive edge in the vulvar and vaginal market; our expectation regarding when we will file an IND update and phase 3 clinical trial protocol, initiate the phase 3 clinical trial, and file an NDA for our estradiol VagiCap™ product; our patent strategy and our expectation regarding the timeframe of patent exclusivity; our expectation that we will file a number of additional patent applications in the fourth quarter of 2013 fiscal year; our expectation that our Opera patent will issue this quarter and will expire in 2031; our belief that our strong cash position and combined revenues from our prenatal franchise are sufficient to fund the execution of our key R&D programs; the impact of the addition of Dr. Mirkin to our team; our goal to have all the sites for the phase 3 clinical trial for our combination drug candidate enrolled by December 31, 2013 and to have all the patients in within one year from the start of the phase 3 clinical trial; the attributes, benefits, and impact of the Opera patent; the results of our dialogue with the IP office; our expectation regarding when we will have the results of the PK study for our estradiol VagiCap™ product; our expectation that Senate will bring the compounding legislation to a vote this month and that the compounding legislation will be passed and signed within the next six months; our position on the compounding legislation; our belief that pharmacies will be good customers of our company; our belief that we are on pace to begin the phase 3 clinical trial for our estradiol VagiCap™ product in the second quarter of 2014 fiscal year and that there are no roadblocks; clinical development of a transdermal version of our combination drug product; our plan to proceed only with the clinical and pre-clinical development of the drugs currently in our pipeline; future R&D spend and its relation to how well the trial is going; our plan to develop the bioidentical compounds ourselves before entertaining any partnership offerings at all; and our belief that the growth of the prenatal vitamin business is strong and that the growth is going in the right direction are forward-looking statements within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995. We caution that these statements are qualified by important factors that could cause actual results to differ materially from those reflected by such forward-looking statements. These forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially, including but not limited to: timely and successful completion of clinical studies and the results thereof; challenges and costs inherent in product marketing; the risks and uncertainties associated with economic and market conditions; risks and uncertainties associated with our business and finances in general; and other risks detailed in our filings with the U.S. Securities and Exchange Commission including our annual report on Form 10-K filed on March 12, 2013, reports on Form 10-Q and Form 8-K, and other such filings.

We do not have, and expressly disclaim, any obligation to release publicly any updates or any changes in our expectations or any change in events, conditions, or circumstances on which any forward-looking statement is based.

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits.*

Exhibit
Number

Description

[99.1](#)

[Transcript of conference call and webcast conducted on November 4, 2013](#)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 6, 2013

THERAPEUTICSMD, INC.

By: /s/ Daniel A. Cartwright
Name: Daniel A. Cartwright
Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit
Number

Description

99.1 Transcript of conference call and webcast conducted on November 4, 2013

TXMD Q3 2013 Earnings Conference Call

November 4, 2013

4:30 PM EST

Edited Transcript

Corporate Participants

Lisa Wilson - In-Site Communications – Investor Relations for TherapeuticsMD, Inc.

Dan Cartwright – TherapeuticsMD, Inc. – Chief Financial Officer

Rob Finizio – TherapeuticsMD, Inc. – Co-Founder and Chief Executive Officer

Conference Call Participants

Annabel Samimy – Stifel Nicolaus – Analyst

Nathan Cali – Noble Financial Group – Analyst

Oren Livnat – Jefferies – Analyst

Andy Hsieh – Cowen – Analyst

PRESENTATION

Operator

(Operator Instructions)

Lisa Wilson

Thank you for joining us this afternoon for TherapeuticsMD's third quarter 2013 financial results conference call. I'm Lisa Wilson of In-Site Communications, Investor Relations for TherapeuticsMD. With me today are Rob Finizio, Co-Founder and Chief Executive Officer, and Dan Cartwright, Chief Financial Officer of TherapeuticsMD.

By now you should have received a copy of our press release issued today after the close of market. If you have not received it, you may access it through the investor relations section at our website.

Before we get started, I would like to remind everyone that any forward-looking statements made during the call are protected under the Safe Harbor of the Private Securities Litigation and Reform Act. Such forward-looking statements are based upon current expectations, and there can be no assurance that the results contemplated in these statements will be realized. Actual results may differ materially from such statements due to a number of factors and risks, some of which are identified in our press release and our annual and quarterly reports filed with the SEC. These forward-looking statements are based on information available to TherapeuticsMD today and the Company assumes no obligation to update statements as circumstances change.

A telephone replay of this call will be available shortly after the call's completion through Monday, November 18th; you'll find the dial-in information in today's press release. The archived webcast will be available for 30 days on the Company's website at TherapeuticsMD.com.

For the benefit of those who may be listening to the replay or archived webcast, this call was held and recorded on November 4th of 2013. Since then, TherapeuticsMD may have made announcements related to the topics discussed, so please reference the Company's most recent press releases and SEC filings.

With that, I'd like to turn the call over to Dan Cartwright.

Dan Cartwright

Thanks Lisa, and good afternoon everyone.

For the three months ended September 30, 2013, net revenue was \$2.3 million compared with net revenue of \$1.0 million for the three months ended September 30, 2012. The increases were directly attributable to a combination of increases in the number of physicians writing prescriptions for our products, the productivity of our sales force, the average net sales price of our product, and the new prescription products introduced in March, April, May and November 2012.

Cost of goods sold increased by \$342 thousand, or 111%, for the third quarter of 2013, compared with the prior year quarter.

Research and development expense increased to \$4.1 million for the third quarter of 2013 compared with \$1.7 million for the third quarter of 2012, because of the costs incurred in the development of our hormone replacement therapy product candidates, including the initiation of two clinical trials.

Sales, general and administrative expenses increased to \$4.8 million during the third quarter of 2013 compared with \$ 2.9 million for the third quarter of 2012.

As a result, our operating loss was \$ 7.2 million for the third quarter of 2013 compared to \$3.9 million for the third quarter of 2012.

Other non-operating expense increased by \$93 thousand for the third quarter of 2013 compared with the comparable quarter in 2012. This increase resulted primarily from the amortization of financing costs of \$448 thousand offset by interest expense and loss on extinguishment of debt.

As a result, net loss for the third quarter of 2013 was \$7.7 million, or \$0.06 per basic and diluted share, compared with a net loss of \$4.3 million, or \$0.04 per basic and diluted share, for the third quarter of 2012.

Cash and cash equivalents were \$59.6 million at September 30, 2013 as compared to \$34.4 million at June 30, 2013 and \$1.6 million at December 31, 2012.

This includes approximately \$30.4 million that we raised during the quarter through the sale of 13,750,000 shares of our common stock at \$2.40 or \$2.23 per share net of underwriters discounts. We are pleased to have welcomed new institutional investors through this underwritten offering.

With that, I'll turn the call over to Rob Finizio to discuss the business in greater detail.

Rob Finizio

Thanks, Dan and welcome to TherapeuticsMD's inaugural earnings call. I'm pleased to report the growing revenues from our legacy prenatal nutrition products and the progress we are making to advance our pipeline of innovative

hormone therapy candidates. I'm going to touch on our strategy behind the current business and then discuss our growth opportunity.

Our current revenue growth stems from our prenatal business. The key element here is that the vitamin business has enabled us to develop infrastructure that will be crucial to launching our hormone therapy products going forward. Our reps are building strong relationships with the OB/GYN community, which is key call-point for our hormone therapy products, assuming clinical success and regulatory approvals. Our robust sales and distribution network is recognized and respected by payers, physicians and patients alike. The prenatal business has also enabled us to build a brand recognition and trust with women.

The focus of our business is hormone therapies, an area that has largely been overlooked for close to a decade. Today, there is growing medical consensus about the value of bio-identical hormone therapy. I'm going to go through our pipeline regarding the hormone therapy candidates under development.

We expect the first NDA we will file to be for 12-002, our low-dose oral progesterone candidate for the treatment of secondary amenorrhea. This is the cessation of menses for 3-6 months or more in otherwise healthy women that once had a period. To reverse this condition, the OB/GYN will use an estrogen primed, progesterone challenge test. In a positive test, a withdrawal bleed usually occurs two to seven days after the challenge in the second cycle, and the Agency looks for complete secretory change following a biopsy in the third cycle.

Our candidate is a lower-dose natural progesterone, delivered orally. Unlike the market leader, Prometrium, which uses micronized progesterone suspended in peanut oil, we are using solubilized progesterone, which has demonstrated several benefits including a lower first-pass effect, lower blood levels, less metabolites, and a 25% increase in bioavailability. It is also non-allergenic, because we removed the peanut oil.

In PK trials, our candidate at the 150 mg test dose was found to be bioequivalent to a 200 mg dose of Prometrium. We believe our solubilized progesterone is behind this important attribute, and we are seeking to establish that our 300 mg dose is clinically equivalent to that of the 400mg dose of Prometrium.

We are on track to initiate a phase 3 clinical trial, called the SPRY trial, this quarter. It will enroll 180 women with secondary amenorrhea, randomized into three equal arms. In the two treatment arms, subjects will receive either the 225mg dose, or the 300mg dose. The third arm will be placebo.

Clinical endpoints are withdrawal bleeding and complete secretory change. I'll give more details once we initiate the trial. Assuming we are up and running this quarter, we expect to announce data by the end of 2014 and file an NDA by the end of 2014, or at the latest very early 2015, again assuming positive results.

Our next candidate is 12-001, our combination product, it's an investigational drug that combines bio-identical hormones - 17 β -estradiol and progesterone into a single dose. We believe our novel combination of solubilized, natural API may provide a safer and more effective alternative compared to current products, as they are the same molecular structures as the body naturally produces.

The benefits of progesterone over progestins has been established in numerous clinical trials. These include a more favorable profile for breast cancer, cardiovascular disease, lipid side effects, and improved carbohydrate metabolism, as well as improved sleep efficiency.

The benefits of estradiol over conjugated equine estrogen has been making headlines. Over the last 2 months, publications in peer reviewed journals including JAMA have highlighted that treatment with oral conjugated estrogens was associated with a higher incidence of venous thrombosis and myocardial infarction. Conjugated estrogen use when combined with Medroxyprogesterone Acetate, also known as MPA, showed breast cancer risk persisted for 13 years after discontinuation of use.

During the third quarter, we initiated the REPLENISH Trial, a pivotal phase 3 clinical trial to measure the safety and efficacy of 12-001 in treating the symptoms of menopause.

Patient enrollment is underway, and we continue to add locations throughout the country. We have a target of around 50 centers in the US. We are about half-way through enrollment of the centers and are extremely happy with the progress thus far.

Clinical endpoints of the REPLENISH Trial include a reduction in frequency and severity of hot flashes over a 12 week period, and a reduction in the incidence of endometrial hyperplasia, for one full year, which is a key concern for women with an intact uterus with estrogen, and in accordance with FDA's Guidance for Estrogen and Progestins.

In terms of timing, we aim to conclude the REPLENISH Trial and announce data by the end of 2015, followed by an NDA filing with the FDA, again assuming positive results.

Turning to our 12-004, our estradiol VagiCap candidate, which we are developing for the treatment of vulvar and vaginal atrophy, also known as VVA.

VVA is a condition triggered by the decrease in estradiol that occurs after a woman's hot flashes have stopped and a new lower estradiol level has been established in the body. If untreated, the symptoms get worse over time and continual therapy is required. Lower estradiol levels cause a reduction in superficial cells in the vagina and an increase in parabasal cells as well. Additionally, the vagina changes from acidic to basic as seen by an increase in pH. According to NAM, the North American Menopause Society, VVA is estimated to affect as many as 50% of postmenopausal women.

The global VVA market was estimated at \$1.6 billion dollars in 2011, and is projected to grow to \$3.1 billion dollars by 2019. Last fiscal year, U.S. sales totaled \$1 billion with no generic products.

Recently the North American Menopause Society issued a new position statement on VVA stating that estrogen therapy is the most effective treatment for moderate to severe symptoms, and that low-dose vaginal estrogen is the preferred treatment in women for whom VVA symptoms are the only menopausal symptoms presenting. The updated NAMS statement further states that low-dose vaginal estrogen therapy may be continued as long as symptoms are present.

In-market products for VVA include the market leader, a conjugated equine estrogen delivered in a vaginal cream, and several vaginal estradiol products. The creams are messy, with administration via a reusable plunger device; the tablets are difficult to use; and may be dislodged during the course of normal activities. We believe that our estradiol VagiCap product, with its simple-to-use, patient-friendly attributes will have a competitive edge in this market.

In a placebo-controlled phase 1 pilot study of 48 menopausal women, treatment with a 10µg dose of 12-004 improved objective measures of VVA over a two-week period versus placebo. Statistically significant differences were found between the treatment and the placebo groups, with the treatment group showing a positive change in the Maturation index, which is cell composition, and registering a pH more closely resembling that found in a premenopausal woman with healthy, non-atrophic vaginal tissue.

Based on these findings, we intend to file an IND update and phase 3 study protocol for this candidate with FDA. Patients will be randomly assigned to one of three arms to receive 10 mcg, 25 mcg, or placebo VagiCap, once-daily, for 14 days and then twice a week over the remaining 10-week period. Clinical endpoints in this study include cell change, lowering of vaginal pH, and a reduction in the incidence of the most bothersome symptoms of VVA.

Our goal is to initiate the phase 3 study in Q2 of 2014. Assuming positive results, this would position us for a mid-year 2015 filing.

Ok, unto IP. Our IP team has developed a multi-faceted patent strategy that is being implemented to cover various aspects of our technology in addition to our current portfolio of pending applications.

We continue to strengthen our IP around our product pipeline and technologies. Right now we have nine patent applications filed in the U.S., seven of which cover various aspects of our candidates that we believe will give us patent exclusivity through 2032. We also anticipate filing a number of additional patent applications in Q4 of 2013 this quarter.

This month, we also expect our Opera patent to issue. Opera is our reporting and analysis software, which is anticipated to expire in 2031.

We believe that our strong cash position, combined with revenues from our prenatal franchise, is sufficient to fully fund the execution of these key R&D programs.

We believe our ability to execute is further strengthened by the recent addition to our team of Dr. Sebastian Mirkin as Chief Medical Officer. Dr. Mirkin joined us from Pfizer, where as Global Head of Women's Health Clinical Research and Development, he oversaw the development and successful marketing authorization of Duavee, a menopausal combination product approved by the FDA last month. We believe his work on the first new combination hormone product to come to market in more than nine years could increase the likelihood of a positive outcome for our portfolio of novel bio-identical therapeutics for hormone therapy.

With that said, operator, please open the call for questions.

QUESTION AND ANSWER

Operator

(Operator Instructions)

Annabel Samimy, Stifel Nicolaus.

Annabel Samimy

Hi guys, thanks for taking my questions, I have a few. I guess the first I want to know about, you mentioned you were about 50% enrolled in the sites for the combination trial. Could you give us an expectation around enrollment for the actual patients in the trial and what the timing of that might be?

Rob Finizio

I just want to clarify your question there, because it's kind of two within one. So are you asking for clarification on patient enrollment or are you asking-

Annabel Samimy

-on patient enrollment or patient sites.

Rob Finizio

Got it. We hope to have all the sites enrolled by the end of this calendar year, so that would be December 31, and then we hope to have all patients in within one year from the start of the clinical trial.

Annabel Samimy

Ok.

Rob Finizio

Alright?

Annabel Samimy

Sure. And just on the patents that you mentioned. So you expect the Opera patent to be issued within a month. Can you explain to us the significance of this reporting analytics software and when, what are some of the activities on the other patent applications that are outstanding and I'm assuming that it has to do with the formulation patents. Can you give us a status on that?

Rob Finizio

Sure. So as we've stated previously today, the Opera patent we believe will issue this quarter. It is more significant, look at it more as a phase 4 reporting tool, because it is very unique. It is something we've used back in the HIT world. It will have a lot of impact when we achieve FDA approval and post-launch to be able to streamline a lot of efficiencies and potential phase 4 studies. So there won't be an immediate impact of that patent I would see in the near future. As far as the other IP goes, there is a tremendous amount of activity going on so as you know and as we've stated before, we've had a strong dialogue with the IP office. We are very bullish and positive on what will be the result there. We also, as I've stated earlier, plan to file a number of additional patent applications this quarter, and I think next quarter we should have accomplished both of those goals.

Annabel Samimy

Ok. Great. And just if I can ask one more question? I think you have a PK study going on in parallel with the pilot program for the estrogen product, the VagiCap. Can you tell us where you are with that PK study and whether anything from that is going to emerge in the coming months?

Rob Finizio

So the clinicals, Annabel, let me just repeat that to make sure that we are clear. So our PK study for the VagiCap that was done against Vagifem, right? That clinical is completed and we are awaiting the results and we expect that in December, mid to late December. Does that answer your question?

Annabel Samimy

Yeah, it does actually.

Rob Finizio

Alright.

Annabel Samimy

Alright, I'll get back in the queue.

Rob Finizio

OK. Thanks. Thanks for joining us today.

Annabel Samimy

Are there any other questions? I'll keep going.

Rob Finizio

If you have more, go ahead and shoot. There is a number more from what I'm told.

Operator

(Operator Instructions)

Nathan Cali, Noble Financial Group.

Nathan Cali

Hey Rob, hey Dan. Congrats. Just wanted to congratulate you on the success over the last several quarters.

Rob Finizio and Dan Cartwright

Thanks Nathan.

Nathan Cali

Just a couple of follow up questions. Have you heard anything as far as what the timing is on the compounding legislation that's ongoing?

Rob Finizio

Yes, actually there is a lot of buzz. Obviously no one knows what Congress will do. The House has passed the legislation, and we do believe the Senate will bring it to a vote this month. Potentially very soon but, you know, it is what it is. Our indication is that we're hearing that it will be this month.

Nathan Cali

Is there any indication that this thing could wrap up within the next six months as far as things getting passed and signed off on?

Rob Finizio

Yes.

Nathan Cali

Ok.

Rob Finizio

And remember Nathan, for the record, I mean we are pro compounding legislation, but at the end of the day, you know, we look to work with compounders pretty closely because pharmacies sell drugs and if they can make more on ours by selling ours than building that one, we think regardless of compounding legislation, they are going to be good customers of ours.

Nathan Cali

Sure. And then as far as the VVA, the phase 3 VVA study, what would be the expectations of you guys initiating that study, you're still waiting on more data from the PK study, but at the close of that and everything is positive, when would you expect to start the VVA study, the phase 3?

Rob Finizio

With a little bit of luck, in Q2. In Q2 of 14. So we are on pace to do that and I don't see any roadblocks at this point.

Nathan Cali

Ok. Is there any potential to add additional candidates to your pipeline down the road?

Rob Finizio

If so, we'll announce it on another earnings call. We've got, so you know, we have three phase 3 programs, which we've disclosed is a lot for our clinical staff to take on. So as you know, we've also announced in the last raise that we in the pipeline are working on a transdermal version of estradiol and progesterone, but that is pre-clinical work and that is a different team. So our team is completely full. So let's get a positive progesterone, a positive VagiCap, and a positive combination trial going, and once we get good result from one of those, hopefully we'll be in a good situation we can take something out of the pipeline and bring it forward. But I just want to set expectations clearly that we are laser focused on that stuff and although our platform can deliver a ton of drugs, that's all we're going to do.

Nathan Cali

That's what I was alluding to and you guys have done such a great job of moving so quickly, just figured I'd ask.

Rob Finizio

Yeah, no problem. Thank you though.

Nathan Cali

Yup. Just one follow-up question for Dan. Any expectations, what we should be looking for on SG&A and R&D over the next 5 quarters? Can we expect some of the same from what we saw in the third quarter for both or maybe a slight increase in R&D, or just sort of, what's the mix there?

Dan Cartwright

Well Nathan, we don't produce forecasts here for the street, but you know as far as R&D work, we know that as we bring on clinical trials, the R&D spend in any quarter could go up or down. It's basically dependent upon actually how well the trial is going. The better the trial is going, of course, the higher the spend, so I think that's how I'm willing to think of it.

Nathan Cali

Sure. Thanks a lot guys.

Rob Finizio

Thank you Nathan.

Operator

(Operator Instructions)

Oren Livnat, Jefferies.

Oren Livnat

Hey guys, it's good to hear you on your first call. You have an unconventional question dial in that I was messing up.

Rob Finizio

Sorry about that.

Oren Livnat

Yeah, no problem. I guess that's how you're doing. A couple of things. On the partnering front, has there been any activity for XUS potential for one or several of your products?

Rob Finizio

You know, as you know, these bioidentical compounds, especially progesterone, are used outside the U.S. for the most part more than in the U.S. So there is a lot of interest out there. We've taken the dilution to raise the money to take these over the goal line ourselves. We're going to get data and we're going to do our best to have successful trials, in my current thinking, before we entertain any partnership offerings at all. If that changes, we'll let you know, but that's the current mindset of the executive management.

Oren Livnat

That's fair enough. I guess on the 12-01, on the combo phase 3 enrollment timing, you get some sites up really quickly and have pretty ambitious goals for that, but the one year timeline that you project for full patient enrollment, given the dynamics of this industry, and that there is lot of people paying cash out of pocket now and there is a huge pent up demand for this stuff in the first place, so I would love to think that you could enroll these numbers faster than a year. So I'm wondering what you guys see as a gating factor? Whether it's just spending or whether it's making sure you just get it right and want to keep a lid on it so the quality doesn't suffer? Just because, trying to figure out how conservative that end of 15 data projection might be?

Rob Finizio

Well you know Oren, it's a good point. It's a great question. How fast is it going to go, you really don't know until you have all your sites enrolled. With any of these clinical trials, until you have all of your sites up and advertising dollars are being pushed out and you see the results, it's really really difficult to tell. Could it be faster? Maybe. Could it be slower? Maybe. So, you know, I think next quarter, next call, we should have all the sites up and going and it should give us some more granularity there.

Oren Livnat

Alright. I guess, switching gears a little bit. You did make some mention of the ongoing patent prosecution for I believe the combo patent. The last I checked which is a little while back, a little stale there, I haven't look at tears or anything, but I know you guys should have already, you have already re-filed a response and maybe by now should have already gotten the latest word from examiners, I'm just wondering, assuming this stuff is public, if you could help us, give us any color on how that's progressing with regards to any hurdles you've passed or bumping into on the IP front.

Rob Finizio

Sure, just to clarify the question. You said patent prosecution, so we were not in any patent litigation or prosecution. Just to be clear.

Oren Livnat

No. I meant in the sense of getting a patent.

Rob Finizio

Because this is a legal record I just want to be careful. So, by the way, very good observation there. I don't have anything I can speak to to this minute, but as I've told you, I am bullish, very bullish on this situation and it will fall where it falls.

Oren Livnat

Thanks so much and we'll chat soon.

Rob Finizio

Thanks a lot Oren. I appreciate you hopping on.

Operator

(Operator Instructions)

Andy Hsieh, Cowen and Company

Andy Hsieh

Hi, thank you for taking my question and congrats on your Spartan-like march to commercialization.

Rob Finizio

Thank you.

Andy Hsieh

So, I'm just wondering about the prenatal vitamin business. So, from 2012 to 2013 it almost doubled in terms of the sales. I'm just wondering how should we think about this business? Is it going to continue to rise at this rate or do you think it will plateau at some time?

Rob Finizio

So, Andy, this is Rob Finizio. So, just to understand your question because there is a whole bunch of questions in there. So, if you look at our sales and if you also look at our deferred revenue, alright? We did 2.3 million in sales, but if you look at this quarter's deferred revenue it went up \$700,000. So, if you take that in consideration versus last quarter or last year, year over year and quarter over quarter, it's significant growth. And as you know I can't forecast at all, it's something that we cannot provide. But the growth thus far, up to this point, has been very very strong and we feel really good about that side of the business. And if you look at the numbers, they are going in the right direction. As you can see we have a total backlog of 1.9, Dan? Is that right?

Dan Cartwright

1.9 of deferred revenue at this point on the balance sheet.

Andy Hsieh

Great, alright.

Rob Finizio

Does that help answer your question?

Andy Hsieh

Yes, yes it does. Thank you for answering my question.

Rob Finizio

Great, thank you. Great. Thanks a lot for listening today. We look forward to updating you as we continue advancing toward our goal of bringing these new products to women at every critical life stage, from pregnancy to menopause and beyond. Have a great day and I thank everyone for attending. Thank you.
